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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/041,036	11/08/2001	James H. Silver	JSILVER.001CP1	3762

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EXAMINER

NASSER, ROBERT L

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 07/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Y.K.

Office Action Summary	Application No. 10/041,036	Applicant(s) SILVER, JAMES H.	
	Examiner Robert L. Nasser	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-43 is/are pending in the application.
- 4a) Of the above claim(s) 31-38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-12, 14-19, 21, 27-30 and 39-43 is/are rejected.
- 7) ☐ Claim(s) 13, 20 and 22-26 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>5</u> . | 6) <input type="checkbox"/> Other: _____ |

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Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-30 and 39-43, drawn to a analyte sensing device, classified in class 600, subclass 345.
- II. Claims 31-38, drawn to a method of reducing the cross sectional profile of an intra-luminal electronic device, classified in class 29, subclass 1.

Inventions I and II are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case, the apparatus can practice a materially different method, such as a method of measuring glucose. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

During a telephone conversation with Mr. Gerard von Hoffman on June 27, 2003 a provisional election was made without traverse to prosecute the invention of Group I, claims 1-30, and 39-43. Affirmation of this election must be made by applicant in replying to this Office action. Claims 31-38 withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 39-41, 43, and 44 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Kaplan.

Claims 39-41 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Schulman figure 2.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4, 9-12, 14, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaplan in view of Winston et al. Kaplan shows two stents connected to a sensor housing, one on either side, for housing among other things, a glucose sensor. The sensor does not extend into the lumen. Winston shows a self-expandable stent that houses sensor 64 and 66 on the inner most lumen surface, where the sensor

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64 and 66 extend into the lumen, where the blood velocity prevents occlusion. The examiner notes that the extent to which the sensors extend into the lumen is not recited in Winston. However, based on the sizes given in the specification for the expanded and compressed configurations, by examining the drawings, it is clear that the sensors extend by the claimed amounts. Hence, it would have been obvious to Kaplan to use the sensor of Winston, as it is merely the use of a known glucose sensor in the art.

Claim 5-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaplan in view of Winston et al as applied to claims 1- 4, 9-12, 14, and 15 above, and further in view of Govari et al. The combination does not have a transmitter in the housing, or a rechargeable battery. Govari et al shows a similar stent with a sensor, where the stent has a transmitter to send data out of the body and a battery for energizing the device, where the battery is charged via an inductive link to an outside device. Hence, it would have been obvious to modify the above combination to include battery and transmitter, as it is merely the inclusion of known circuitry for a stent sensing device in the art.

Claim 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaplan in view of Winston et al as applied to claims 1-4, 9-12, 14, and 15 above, and further in view of Schulman et al. Schulman shows a glucose sensor that meets the claim language. Hence, it would have been obvious to modify the above combination to use such a sensor, as it is merely the substitution of one known equivalent sensor for another.

Claims 19, 21, 22, 29, and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaplan in view of Govari et al. Kaplan shows two stents connected to a sensor housing, one on either side, for housing among other things, a glucose sensor. It does not show the power source or circuitry in the body Govari et al shows a stent sensing device where the power supply is located on the stent itself. Hence, it would have been obvious to modify Kaplan to use this kind of power source, as it is merely the substitution of one known power source for another.

Claim 27 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaplan in view of Govari et al et al as applied to claims 19, 21, 22, 29, and 30 above, and further in view of Schulman et al. Schulman shows a glucose sensor that meets the claim language. Hence, it would have been obvious to modify the above combination to use such a sensor, as it is merely the substitution of one known equivalent sensor for another.

Claims 13, 20, and 22-26 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert L. Nasser whose telephone number is (703) 308-3251. The examiner can normally be reached on MAXIFLEX.

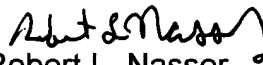
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (703) 308-3130. The fax phone numbers for the organization where this application or proceeding is assigned are (703)

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308-0758 for regular communications and (703) 308-0758 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

ROBERT L. NASSER
PRIMARY EXAMINER


Robert L. Nasser
Primary Examiner
Art Unit 3736

RLN
June 29, 2003